ATTACHMENT D

FEB 2 3 2007

SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health Alaris Products

Signature Edition® Infusion System

Models 710X and 720X

SUBMITTER'S NAME: **Cardinal Health 303, Inc.**
dba Cardinal Health, Alaris Products
10221 Wateridge Circle
San Diego, CA 92121-2772
(858) 458-7830
(858) 458-6114 FAX

CONTACT PERSON: **Stacy L. Lewis**
Principal Regulatory Affairs Specialist

DATE PREPARED: **January 26, 2007**

DEVICE NAME:
Proprietary Name: Signature Edition® Infusion System
Common Name: Infusion Pump
Classification Name: Pump, Infusion, FRN (880.5725)

PREDICATE DEVICE: Signature Edition® Infusion System (K931549), October 12, 1993

DEVICE DESCRIPTION

The subject of this Special 510(k) submission is the Signature Edition® Infusion System Models 710X and 720X. This device is essentially the same as the originally submitted predicate device, the Signature Edition® Infusion System (submitted as the Models EZ 1 and EZ 2 Infusion Pumps, K931549, October 12, 1993), with the exception of the device

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modification provided in this submission. Other prior submissions include K032147 (Signature Edition Infusion System), which covered minor aggregate changes to the Signature Edition Infusion System and included all Signature Edition models (700X, 710X, 720X, 713X and 723X).

The same device modification provided in this submission was also submitted for the Signature Edition® Gold Infusion System, Models 713X and 723X (K063288) and was cleared to market on November 28, 2006.

The electrical volumetric pumps are used to control the rate or monitor the flow of solution or medication for delivery of drugs, fluids, and blood products. Infusion pumps have been proven to be useful in applications such as continuous epidural anesthesia, administration of IV cardiovascular drugs, chemotherapy, and blood transfusions.

SUBSTANTIAL EQUIVALENCE

With the exception of the device modification presented in this submission, the Signature Edition® Infusion System is essentially the same as the originally submitted predicate device. The intended use, principles of operation, fundamental scientific technology, method of manufacture, and application are essentially the same.

INTENDED USE

The intended use of this device has not changed from the original submissions in terms of content or intent:

The Signature Edition® Infusion System is intended for use in today's growing professional healthcare environment including healthcare facilities, home care, and medical transport that utilize infusion systems for the delivery of fluids, medications, blood and blood products.

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K070268

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The Signature Edition® Infusion System is indicated for continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral, or irrigation of fluid spaces.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Signature Edition® Infusion System and the predicate devices has been performed. The results of this comparison demonstrate that the modified Signature Edition® Infusion System is equivalent in technological characteristics to the unmodified device and that the fundamental scientific technology of the predicate device has not been altered.

K070268

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2007

Ms. Stacey L. Lewis
Principal Regulatory Affairs Specialist
Cardinal Health 303, Incorporated
10221 Wateridge Circle
San Diego, California 92121-2772

Re: K070268
Trade/Device Name: Signature Edition® Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: January 26, 2007
Received: January 29, 2007

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment B

INDICATIONS FOR USE

510(k) Number: K070268 (To Be Assigned By FDA)

Device Trade Names: **Signature Edition® Infusion System**

Indications For Use:

The Signature Edition® Infusion System (Models 710X and 720X) is intended for use in today's growing professional healthcare environment including healthcare facilities, home care, and medical transport that utilize infusion systems for the delivery of fluids, medications, blood and blood products.

The Signature Edition® Infusion System is indicated for continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral, or irrigation of fluid spaces.

Prescription Use ___X___ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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